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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,724	01/03/2001	Masafumi Kitakaze	58777.000003	1212

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EXAMINER
MITRA, RITA

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/22/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/752,724	KITAKAZE, MASAFUMI	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 December 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Claims

Applicants' amendment and response to office action dated September 10, 2002, filed on December 10, 2002 in paper #12 is acknowledged. Claims 1, 3, 6 and 8 have been amended. New claims 11-16 have been added. Therefore, claims 1-16 are currently pending and are under examination.

Withdrawal of Objections/Rejections

The objection to disclosure for missing continuing data is withdrawn in light of the amendment to specification at page 1, line 1.

The objection to claim 1 for the repetition of line 2 is withdrawn in light of the amendment to claim 1.

The priority date claimed March 31, 2000 is granted in light of providing an English translation in support of the priority date claimed.

The partial translation of reference D of IDS is acknowledged.

The objection to claims 4, 5, 9 and 10 as being in improper form is withdrawn in view of amendment to claims 3 and 8.

The rejection of claims 1-10 under **35 U.S.C. § 112, second paragraph** is withdrawn in view of Applicants' amendment to claims.

New grounds of Objection/Rejection

New Matter Objection

The amendment filed December 10, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material, which is not supported by the original disclosure, is as follows:

The amendment to page 9 of the specification indicates an additional sentence that reads as "when the administration is made by coronary infusion, a higher dose of the active ingredient

can be administered than in the case of an intravenous administration" is not supported by the original disclosure. No part of specification shows what the added sentence indicates at, also pages 4-6 of response do not address where support for the higher dose is found in the application as filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Rejection under 35 U.S.C. 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-16 are rejected because the amendment to specification at page 9 has no support from the original disclosure (see New Matter objection). Since claims would be read in light of specification would have in part the same interpretation. The response pages 4-6 (paper #12) do not indicate support for higher dose given in the original disclosure.

Rejection under 35 U.S.C. 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is drawn to a method for reducing an infarct region by administering a substance capable of acting on a natriuretic peptide. The word "capable of" is not clear, since it

is not clear whether the substance actually needs to act on a natriuretic peptide receptor or merely has the capability to do so. Amending the claim by deleting the word "capable" would obviate this rejection. Claim 12 is included in the rejection because it is depended on rejected claim and do not correct the deficiency of the claim from which they depend.

Rejection under 35 U.S.C. 102

> The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by Takata et al. (Cardiovascular Research, 32, 286-293, 1996). Takata et al. teach a pharmaceutical composition that comprises an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim1, 4 and 5), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 1), and has cardioprotective effects (claims 1) on myocardial ischemia (claim 3) and reperfusion injury (claim 2) (see abstract; page 287, col 1, lines 12-14 and 24-25; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Therefore, Takata's composition meets the criteria of claims 1-5 of instant application. In response Applicants argue (page 5) that the myocardial protective effect of ANP disclosed by Takata is simply the suppression of arrhythmia such as ventricular extrasystoles or the suppression of the decrease of intra-cellular high energy phosphates, while in contrast the present invention comprises reducing an infarct region resulting from the ischemic necrosis. Further, Applicants assert that they found for the first time that these peptides can reduce an infarct region occurring in a model of acute myocardial infarction invoving ischemia reperfusion. Arguments are not found persuasive because the amended claims and the assertion do not make the compound and composition new, nor does it change the composition. The composition remains unchanged and anticipated.

Takata et al. also teach a method of cardioprotection (claim 6) of myocardial ischemia (claims 8) and reperfusion injury (7) by administering a composition comprising an effective amount of synthetic alpha human ANP (atrial natriuretic peptide) (claim 6, 9 and 10), which increases the level of cyclic guanosine monophosphate (cGMP) (claim 6), and has

cardioprotective effects on myocardial ischemia and reperfusion injury (claims 6, 7, 8), (see abstract; page 287, col 1, lines 12-14 and 24-25, col 2, lines 14-18; page 289, col 1, lines 35-39; Fig. 1 and Table 1). Therefore, Takata's method anticipates claims 6-10 of instant application. In response Applicants argue (page 5) that the myocardial protective effect of ANP disclosed by Takata is simply the suppression of arrhythmia such as ventricular extrasystoles or the suppression of the decrease of intra-cellular high energy phosphates, while in contrast the present invention comprises reducing an infarct region resulting from the ischemic necrosis. However, arguments are not found persuasive because the amended claims and the response fail to address the property of cGMP uptake. Applicants have not shown separability of cGMP uptake from the compound.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

Rita Mitra, Ph.D.
April 14, 2003

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